UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/666,890	09/20/2000	James L. Hartley	0942.2570003/RWE/DRM	9088

7590 05/08/2002

Sterne Kessler Goldstein & Fox PLLC
Attorneys at Law
Suite 600
1100 New York Avenue NW
Washington, DC 20005-3934

EXAMINER
WHISENANT, ETHAN C

ART UNIT	PAPER NUMBER
1634	14

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/666,890	HARTLEY, JAMES L.	
	Examiner	Art Unit	
	Ethan C. Whisenant	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31,32 and 79-82* is/are allowed.

6)☒ Claim(s) *15-30,34,37-42,45-57,60-66,69-75 and 78* is/are rejected.

7)☒ Claim(s) *33,35,36,43,44,58,59,67,68,76 and 77* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The applicant's Response to the Office Action of 19 OCT 01 (paper no. 8) has been entered. The applicant's response was filed and received on 11 MAR 02 and has been entered as paper no. 12. Following the entry of the applicant's amendment , **Claim(s) 15-82** are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

In response to the applicant' s query regarding the response filed 25 JUL 01 and the pending claims (i.e. Section II of the response filed and received on 11 MAR 02)., the examiner apologizes for any confusion and will herein try to set the record straight. The response filed 25 JUL 01 was received on 25 JUL 01 and was entered as paper no. 7. At that time Claims 15-33 were pending. A non-final Office Action followed (i.e. paper no. 8) which was mailed on 19 OCT 01. The applicant then responded with paper nos. 9-12. The amendment as noted above was filed and received on 11 MAR 02 and has been entered as paper no. 12. Most importantly, following the entry of the applicant's amendment , **Claim(s) 15-82** are pending.

Finally, please note that the Terminal Disclaimer filed 25 JUL 01 is proper and has been entered.

SEQUENCE RULES

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

35 USC § 112 - 1ST PARAGRAPH

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

CLAIM REJECTIONS under 35 USC § 112- 1ST PARAGRAPH

4. **Claim(s) 33** is/are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for a method of determining the mass of a unknown nucleic acid wherein the staining intensity of a unknown nucleic acid is determined by comparing the staining intensity of the unknown to a known marker band/ladder.

Clearly one could determine the approximate molecular weight of any nucleic acid fragment as long as the length of the unknown nucleic acid fragment could be determined/estimated. One need only multiply the number of base pairs present in a nucleic acid fragment with the average mass of a dNMP bp to arrive at the answer. However, there is no explanation in the specification as to how one can determine the mass of an unknown nucleic acid (i.e. dsDNA fragment) by comparing the staining intensity of the unknown nucleic acid to the staining intensity of a known marker band/ladder.

35 USC § 112- 2ND PARAGRAPH

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

6. **Claim(s) 23-30** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite in that the phrase "the first container" is nonsequitur and lacks proper antecedent basis in view of the phrase "at least one container" and in view of the fact that there is no second container. Please clarify.

35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

CLAIM REJECTIONS UNDER 35 USC § 102/103

9. **Claim(s) 15-30, 34, 37-39, 45-48, 52-54, 60-63, 69-72, 78** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carlson et al. [EP466404A1(1991)].

Carlson et al. teach a nucleic acid marker ladder which comprises at least 3 nucleic acid fragments wherein the size of each said at least 3 nucleic acid fragments in base pairs is a multiple of an integer (i.e. 10) with respect to at least one of said at least 3 nucleic acid fragments. See, for example, the fragments 730, 910 and 2650 in Figure 1.

Note that the word integer has been accorded its "usual" meaning. {i.e. integer [in't jr] Mathematics. a positive or negative whole number or zero; an element of the set { . . . , -2, -1, 0, 1, 2, . }}. This definition was obtained from The Academic Press Dictionary of Science and Technology. Therefore 1 is an integer.

Also note that the intended use limitations recited in some of the claims (e.g. 15) carries little weight because the applicant is claiming a product and it is well established that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey* , 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963).

Finally note that the way in which the product is to made also carries little weight because a product is not limited by the why it is made but rather by its structure. If the product in a claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. "*In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

10. **Claim(s) 15-30, 34, 37-42, 45-51, 52-57, 60-66, 69-75, 78** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over The Gibco BRL Catalog (1991/1992).

The Gibco/BRL Catalog teach a nucleic acid marker ladder (i.e. the biotinylated ΦX174/HinfI fragments) which comprises at least 3 nucleic acid fragments wherein the size of each said at least 3 nucleic acid fragments in base pairs is a multiple of an integer (i.e. 10, 25, 50 and 100) with respect to at least one of said at least 3 nucleic acid fragments. See, for example, the fragments 100, 200 and 500 in the first figure on page 317.

Also note that the intended use limitations recited in some of the claims (e.g. 15) carries little weight because the applicant is claiming a product and it is well established that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey* , 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963).

Finally, note that the way in which the product is to made also carries little weight because a product is not limited by the why it is made but rather by its structure. If the product in a claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. "*In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

CLAIM OBJECTIONS

11. **Claim(s) 33, 35-36, 43-44, 58-59, 67-68, and 76-77** is/are objected to because they are dependent upon a rejected independent base claims

ALLOWABLE SUBJECT MATTER

12. **Claim(s) 31-32, 79-82** is/are allowable over the prior art of record.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

13. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new grounds of rejection.

CONCLUSION

14. **Claim(s) 31-32 and 79-82** is/are allowable while Claim(s) 15-30 and 33-78 and is/are rejected and/or objected to for the reason(s) set forth above.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

ETHAN C. WHISENANT
PRIMARY EXAMINER